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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/732,843

Applicant(s)

CICENAS ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the RCE filed 8/8/2007. Claims 1 and 10 are amended. Claims 14-15 are cancelled. **Claims 1-13 and 16-20** remain pending.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claim 16** is rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al (US Pat No. 5526822).

4. Burbank et al disclose a biopsy device comprising:

a hollow biopsy needle (44) having a lateral tissue receiving port (46);

a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port;

a sample tube or “tubular knock out pin” (92) having an open distal end defining a distal opening defining a generally circular plane transversely intersecting a central axis of said sample tube, a proximal end in communication with a source of vacuum (Col.14, line 47-50), said sample tube releaseably supported on the biopsy device and advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle comprising an internally threaded, rotatably driven component for advancing and rotating the cutter including internally threaded “cannular inner cutter collet” (762), “motor” (780), and rotatably driven

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“drive gear” (776) and “indexing gear” (772), best seen in Figure 17 (Col.19, line 49-67), collectively used for advancing and rotating the cutter.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-13 and 16-20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al (US Pat No. 5526822) in view of Banik et al (US Pat No. 6053877).

7. In regards to **Claim 1**, Burbank et al disclose a biopsy device comprising of a hollow biopsy needle (44) having a tissue receiving port (46), a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port, and a sampling mechanism including “tubular knockout pin” (92) having an open distal end sized for receiving a tissue sample severed by the hollow cutter and advanceable within the cutter (Col.13: 38-41).

8. However, Burbank et al do not explicitly disclose said sampling mechanism is a sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, nor does Burbank et al disclose the cutter has a plurality of holes spaced from the distal end of the cutter and positioned for providing vacuum axially through the cutter when multiple tissue samples are disposed within the sample tube within the cutter.

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9. Banik et al disclose an effective sampling mechanism comprising a sample tube 20 advanceable within a hollow cutter 14, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, the sample tube being releasably supported on the device such that the sample tube and at least one tissue sample stored therein may be removed from the device without disassembling the device (Col.10: 3-17), best seen in Figures 2 and 5D, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

10. Burbank et al also disclose a biopsy device wherein a hollow biopsy needle 644 with a tissue receiving port 646 has a plurality of holes 650 spaced from the distal end and are positioned for providing vacuum axially through the hollow biopsy needle by way of vacuum chamber 652, best seen in Figure 16 (Col.19: 24-35), to effectively draw in larger and more uniform samples.

11. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy device of Burbank et al to have a sampling mechanism comprising a sample tube advanceable within the hollow cutter, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, and the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, as taught by Banik et al, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

12. Furthermore, it would also have been obvious to one of ordinary skill in the art at the time the invention was made to modify the hollow cutter of the biopsy device of Burbank et al as

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modified by Banik et al, such that the cutter has a plurality of holes spaced from the distal end of the cutter and wherein the holes are positioned for providing vacuum axially through the cutter, as taught by Burbank et al, to effectively draw in samples even when multiple tissue samples are disposed within the sample tube within the cutter.

13. In regards to **Claim 2**, Banik et al disclose the sample tube is adapted to store multiple samples in an end to end configuration, best seen in Figure 5d.

14. In regards **Claim 3**, Burbank et al and Banik et al disclose a vacuum source in communication with the sample tube as defined above (Burbank et al Col.14, line 47-50).

15. In regards to **Claims 4-6**, Burbank et al and Banik et al disclose the sample tube as defined above advanced by a pneumatic cylinder (Burbank et al Col.14, line 40-43).

16. In regards to **Claim 7**, Burbank et al disclose an apparatus for advancing and retracting the cutter (68) within the biopsy needle. Specifically, Burbank et al disclose an "inner cutter linear driver" (88) to move the cutter proximally and distally, best seen in Figure 2 (Col.14, line 61-64).

17. In regards to **Claim 8**, Burbank et al and Banik et al disclose an apparatus for advancing and retracting the sample tube as defined above within the cutter (68), referred to as "tubular knock out pin linear driver" (112), best seen in Figure 2 (Burbank et al Col.14, line 40-43).

18. In regards to **Claim 9**, Burbank et al disclose the hollow needle (44) comprising a lateral tissue receiving port (46) spaced from the distal end of the needle, best seen in Figure 4.

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19. In regards to **Claim 10**, Burbank et al in combination with Banik et al disclose the invention above but do not disclose the sample tube comprises a vacuum lumen and a sample lumen. However, Burbank et al do disclose a biopsy device comprising a hollow biopsy needle 644 that comprises a vacuum lumen 652 and a sample lumen 646 wherein the vacuum lumen extends along side of at least a portion of the sample lumen, best seen in Figure 16, to effectively provide uniform vacuum to draw in larger and more uniform tissue samples (Col.19: 24-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sample tube of Burbank et al and Banik et al to comprise both a vacuum lumen and a sample lumen, wherein the vacuum lumen extends along side of at least a portion of the sample lumen, as taught by Burbank et al, to effectively provide uniform vacuum to draw in the tissue samples.

20. In regard to **Claims 11-12**, Banik et al disclose the sample tube 20 comprises a tube wall feature such as notch or indentation 32, 32' adjacent the distal end of the sample tube, best seen in Figure 2.

21. In regards to **Claim 13**, Burbank et al disclose a rotating journal for rotating and advancing the cutter. The rotating journal is defined as the "cannular inner cutter elongate indexing gear" (72), which is connected to "cannular inner cutter drive motor" (80) and "inner cutter linear driver" (88) to rotate and advance the cutter, respectively, best seen in Figure 2 (Col.13, line 28-37; Col.18 line 22-24).

22. In regards to **Claim 16**, Burbank et al disclose a biopsy device comprising:

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a hollow biopsy needle (44) having a lateral tissue receiving port (46);

a hollow cutter (68) advanceable within the biopsy needle to sever tissue received within the tissue receiving port;

a sampling mechanism including “tubular knock out pin” (92) having an open distal end defining a distal opening defining a generally circular plane transversely intersecting a central axis of said sample tube, a proximal end in communication with a source of vacuum (Col.14, line 47-50), said tubular knock out pin advanceable within the cutter;

a drive mechanism for advancing and rotating the cutter within the biopsy needle comprising an internally threaded, rotatably driven component for advancing and rotating the cutter including internally threaded “cannular inner cutter collet” (762), “motor” (780), and rotatably driven “drive gear” (776) and “indexing gear” (772), best seen in Figure 17 (Col.19, line 49-67), collectively used for advancing and rotating the cutter.

23. However, Burbank et al do not explicitly disclose said sampling mechanism is a sample tube releasably supported on the biopsy device. Banik et al disclose an effective sampling mechanism comprising a sample tube 20 advanceable within a hollow cutter 14, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, the sample tube being releasably supported on the device such that the sample tube and at least one tissue sample stored therein may be removed from the device without disassembling the device (Col.10: 3-17), best seen in Figures 2 and 5D, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

24. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the biopsy device of Burbank et al to have a sampling mechanism

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comprising a sample tube advanceable within the hollow cutter, the sample tube having with an open distal end sized for receiving a tissue sample severed by the hollow cutter, and the sample tube being releasably supported on the biopsy device such that the sample tube and at least one tissue sample stored therein may be removed from the biopsy device without disassembling the biopsy device, as taught by Banik et al, as an effective sampling mechanism that advantageously allows collection of multiple samples at one time.

25. In regards to **Claim 17**, Burbank et al disclose a method of obtaining a tissue sample comprising the steps of:

drawing tissue into a tissue receiving port (46) of a hollow biopsy needle (44);

advancing a hollow cutter (68) in the needle to sever a tissue sample;

a sampling mechanism including knock out pin (92) (Col.17: 48-51).

26. However Burbank et al do not explicitly disclose the sampling method comprising the step of advancing a hollow sample tube in the cutter to position the tissue sample in the sample tube, wherein the tissue sample is axially received in the hollow sample tube through an open distal end during the act of advancing the hollow sample tube, and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube.

27. Banik et al disclose an effective sampling mechanism comprising a hollow sample tube (20) with an open distal end, wherein the hollow sample tube is advanced in a hollow cutter (14) to position a tissue sample in the sample tube, wherein the tissue sample is axially received in the hollow sample tube through the open distal end during the act of advancing the hollow sample tube (Col.6: 37-48), and then removing the sample tube from the hollow cutter with at least one

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tissue sample positioned within the sample tube (Col.10: 3-17), as an effective sampling mechanism that allows collection of multiple samples at one time, best seen in Figures 2 and 5D.

28. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the sampling mechanism of Burbank et al with the sampling mechanism of Banik et al such that a hollow sample tube is advanced in the cutter with the distal end of the hollow cutter disposed in the needle, to position the tissue sample in the sample tube, the tissue sample is axially received in the hollow sample tube through an open distal end during the act of advancing the hollow sample tube, and then removing the sample tube from the hollow cutter with at least one tissue sample positioned within the sample tube, as an equally effective sampling mechanism that also advantageously allows the simultaneous collection of multiple samples.

29. In regards to **Claim 18**, Banik et al disclose stacking multiple samples in an end to end configuration within the sample tube, best seen in Figure 5D.

30. In regards to **Claim 19**, Burbank et al in combination with Banik et al disclose a method comprising providing a vacuum through a sample tube (578) (Col.15, line 6-8, also Col.14, line 47-50).

31. In regards to **Claim 20**, Burbank et al in combination with Banik et al disclose a method comprising providing axial vacuum in the cutter through the sample tube with at least one sample disposed the sample tube for the reasons elaborated above.

Response to Arguments

32. Applicant's arguments filed 8/8/2007 regarding **Claims 17-20** have been fully considered but they are not persuasive. Applicant contends that Burbank et al does not teach the tissue sample positioned in knock out pin 292 and only teaches that the sample may be suctioned through the knock out pin and as such, the combination of Burbank et al and Banik et al result only from improper hindsight. However, although Examiner agrees that Burbank et al do not explicitly teach the tissue sample positioned in knock out pin 292, it is noted that as elaborated above, the substitution of one sampling means for another is obvious to one of ordinary skill in the art in light of the teachings of Banik et al, wherein the sample mechanism of Burbank et al including knock out pin 292 is replaced by the sample tube 20 of Banik et al for the reasons motivated above.

33. Furthermore, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

34. Applicant's arguments regarding **Claim 16** have been fully considered but they are also not persuasive. Applicant contends that Burbank et al does not knock out pin 292 to serve as a sample tube for storing tissue. However, it is noted that said claim does not recite said sample tube for storing tissue. Applicant also contends that the knock out pin 292 is not releasably

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supported on the biopsy device. However, it is noted that releasably simply is defined as “capable of being released,” the interpretation of which as applied to Burbank et al means that said knock out pin is capable of being released from said biopsy device. Once again, it is noted that said claim does not recite the sample tube to be removed from the biopsy device, only “releasably supported.”

35. Applicant's arguments with respect to **Claims 1-13** have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
10/15/2007


